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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------------|-------------|-------------------------------|---------------------|------------------|
| 10/522,456 | 01/21/2005 | Albertina Maria Eduarda Arien | JAB1715-US-PCT | 4146 |
| 27777 | 7590 | 11/12/2009 | EXAMINER | |
| PHILIP S. JOHNSON | | | AHMED, HASAN SYED | |
| JOHNSON & JOHNSON | | | | |
| ONE JOHNSON & JOHNSON PLAZA | | | ART UNIT | PAPER NUMBER |
| NEW BRUNSWICK, NJ 08933-7003 | | | 1615 | |
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| | | | 11/12/2009 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/522,456 | ARIEN ET AL. | |
| | Examiner | Art Unit | |
| | HASAN S. AHMED | 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 24 July 2009.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,2 and 12-15 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1,2 and 12-15 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 4/29/09.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) Notice of Informal Patent Application

6) Other: _____.

DETAILED ACTION

- Receipt is acknowledged of applicants' appeal brief, filed on 24 July 2009 and second supplemental IDS, filed on 29 April 2009.
- After further consideration, the finality of the rejection of the last Office action is withdrawn and prosecution reopened. The following are new grounds of rejection.

* * * * *

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,211,249 (“Cohn”) (cited on the IDS filed on 21 January 2005).

Instant claim 1 recites a diblock copolymer of formula A-B wherein polymer block A represents a linear pharmaceutically acceptable hydrophilic polymer with a molecular weight <1,000, and polymer block B represents a polymer comprising at least two different monomers selected from glycolic acid, propiolactone, gamma-butyrolactone, delta-valerolactone, gamma-valerolactone, epsilon-caprolactone, trimethylene carbonate, p-dioxanone, tetramethylene carbonate, epsilon-lactone, 1,5-dioxepan-2-one wherein the diblock copolymer is liquid at a temperature below 50 degrees Celsius.

Cohn discloses polymeric compositions comprising coupled or cross-linked poly(ester)/polyether AB diblocks (see col. 2, lines 30-32). In a preferred embodiment,

the polyester unit A is derived from the polymerization of monomers selected from, *inter alia*, glycolic acid (see col. 2, line 42), epsilon-caprolactone (see col. 2, line 43), and mixtures thereof (see col. 2, lines 53-54) (reading on instant claims 1 and 2). Cohn further discloses that unit B is a poly(oxyalkylene) molecule with a molecular weight as low as 100 (diethylene glycol) and a preferred molecular weight as low as 550 (see col. 3, lines 1-5) (reading on claim 1).

Regarding the temperatures recited in instant claims 1 and 15, Cohn is silent with respect to the melting points of the disclosed diblock polymers. However, the diblock polymers disclosed in the Cohn reference read on the instant diblock polymers, as currently claimed (see above). “Products of identical chemical composition can not have mutually exclusive properties.’ A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).” See MPEP 2112.01.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,211,249 (“Cohn”) (cited on the IDS filed on 21 January 2005).

The features of instant claim 1 disclosed in Cohn are discussed above. Cohn further teaches that the disclosed diblock polymer may have a molecular weight range of, "as low as several hundred to upwards of 50,000 or more." See col. 38, lines 21-23. This disclosed range overlaps with the molecular weight ranges recited in instant claims 12-15. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a diblock copolymer of formula A-B wherein polymer block A represents a linear pharmaceutically acceptable hydrophilic polymer with a molecular weight <1,000, and polymer block B represents a polymer comprising at least two different monomers selected from, *inter alia*, glycolic acid and epsilon-caprolactone, wherein the diblock copolymer has a molecular weight ranging from 2000 to 10,000 as taught by Cohn. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a copolymer because it may be used to make, "bioabsorbable polymeric material which can be produced in a variety of formulations which have acceptable strength, may be reactive or non-reactive with patient tissue depending upon the desired application, and are bioabsorbable" as explained by Cohn (see col. 2, lines 10-14).

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615